Instruction manual

Slit lamp bon SL-E

GA bon SL-E Rev 1.0 E 281105.doc

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Appendix: EC Declaration of Conformity

1 Introduction

Dear customer

Thank you for purchasing our bon SL-E slit lamp. Please read the operating instructions carefully before using the device. Keep these instruction manual safe for future use.
Please observe the safety instructions.
If you have any further questions, please contact our customer helpline.

Meaning of the symbols in the operating instructions

Caution! Please observe safety instructions with this symbol to prevent personal danger or damage to property.

Important! Indicates particularly important information to maintain the function of the device/system or to extend its life.

Note! Indicates information for correct use so that errors may be avoided.

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bon Optic reserves the right to make changes in the interest of technical development. These operating instructions are not subject to updating.

2 Important information

2.1 System information

Name of Device : bon SL-E

Manufacturer : bon
Optic Vertriebsgesellschaft mbH
Stellmacherstraße 14
D- 23556 Lübeck

2.2 Application and classification

2.2.1 Application (appropriate use)

The slit lamp bon SL-E is used to examine the structures at the front of the eye.

2.2.2 Classification

The slit lamp bon SL-E is a Class 1 non-invasive, active medical device in accordance with the classification regulations of Directive 93/42/EWG on medical devices (MDD).

2.3 Liability

The slit lamp is manufactured according to the current technical status and the recognised safety regulations and is tested in accordance with strict quality criteria.
bon Optic only accepts liability for the safety, reliability and performance of the device if

- any changes or repairs have been carried out by a person authorised by bon Optic to do so.
- the power supply to which the device is connected corresponds to DIN VDE 0100-710.
- the device is operated in accordance with these operating instructions.
- the operator complies to the Ordinance on the Operation of Medical Devices (MPBetreibV).

If the system is assembled, changed or repaired by an unauthorised person, if it is improperly maintained or not used as described in 2.2.1, the manufacturer is no longer liable.

2.4 Scope of delivery

1 x slit lamp bon SL-E

1 x dust shield

1 x focussing light

1 x replacement lamp 6V/20W

1 x non-slip surface

1 x mouth cover with fixing screw

1 x test rod

2 x gearwheel plates

2 x running wheel covers

1 x set of screws

1 x power socket with front cover

Components needed for operation

- Head rest
- Mains adaptor

Special equipment

- Eyepiece for length and angle measurements
- Applanation tonometer
- InLine video package, photo attachment

3 Safety instructions

Please follow the legal requirements on accident prevention and observe the following safety instructions!

Setting-up and assembly:

- The split lamp should not be assembled and operated in damp rooms.
- Ensure that the device is on a level and stable surface during assembly.
- The mains voltage must be the same as stated on the product label.

Operating:

- Do not subject the slit lamp to extremes of temperature. It is recommended that the product be used at temperatures of between +10° C and +40°C.
- The ophthalmometer must not be used in areas where there is a danger of explosion.
- Avoid dropping or splashing water on the device.
- The slit lamp must only be used by authorised persons.
- Do not attempt to move or shake the slit lamp with excessive force. First check whether the adjustment screws have been loosened.
- The moveable arm and slit projector can move up and down between their bases. Make sure you don't squash your hands!
- Do not open the protective cover of the halogen lamp whilst the device is in use. You could be burnt!

Other information:

- Do not pull on the power cable in order to remove the plug from the socket. Pull on the plug directly.
- Ensure that no damage occurs to the cable (e.g. sharp edges, high heat).

4 Description of the device

The bon slit lamp SL-E is a professional universal instrument with 2x magnification adjustment for examination of the front structures of the eye.

4.1 Composition of the slit lamp

Main components:

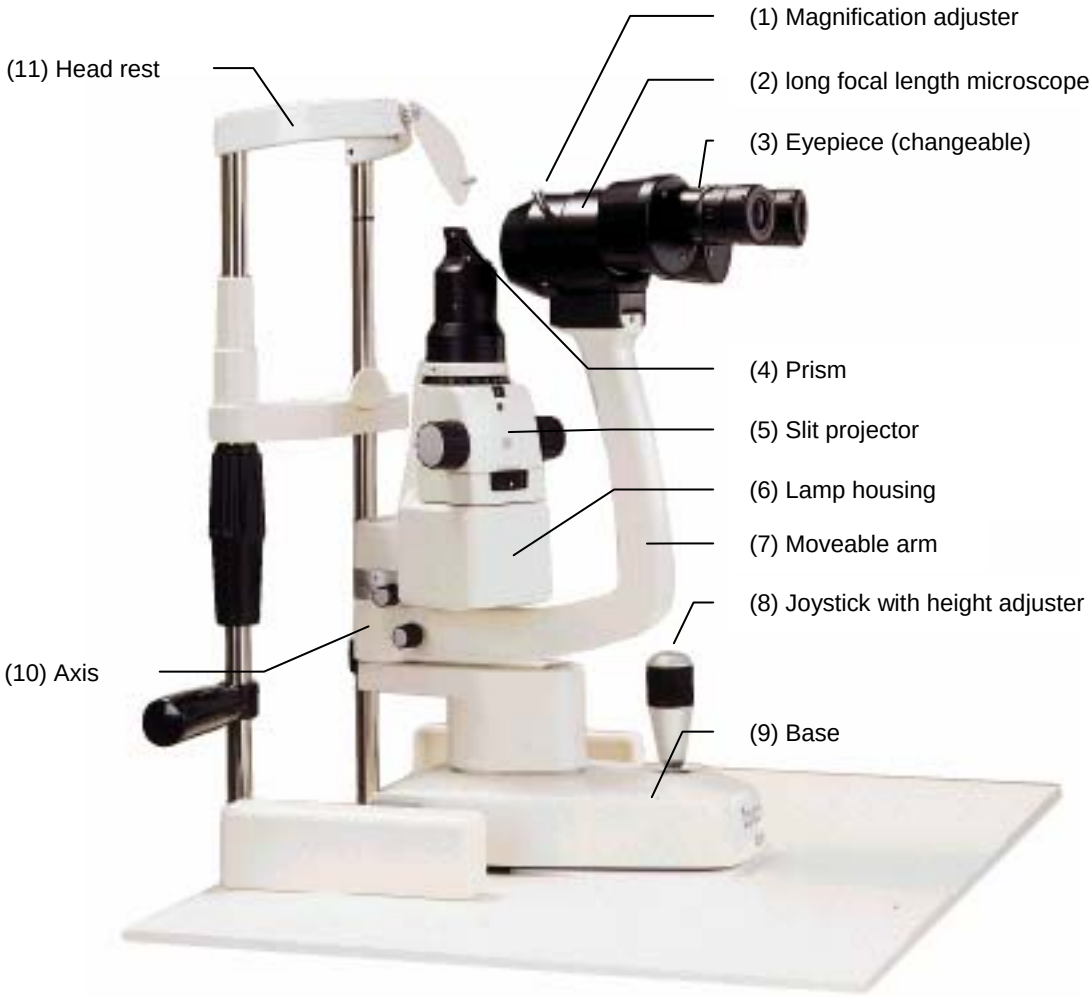


Diagram 4-1: Slit lamp bon SL-E

The slit lamp sits on a base (9) with orthogonal movement. The slit lamp can be moved in an x and y direction using the joystick (8). Moving the joystick from left to right will change the height (approx. 4cm) of both the microscope (2) and the slit projector (5) to line up with the eye being examined. The microscope and slit projector can be moved independently on the joint axis (10).

4.2 Microscope

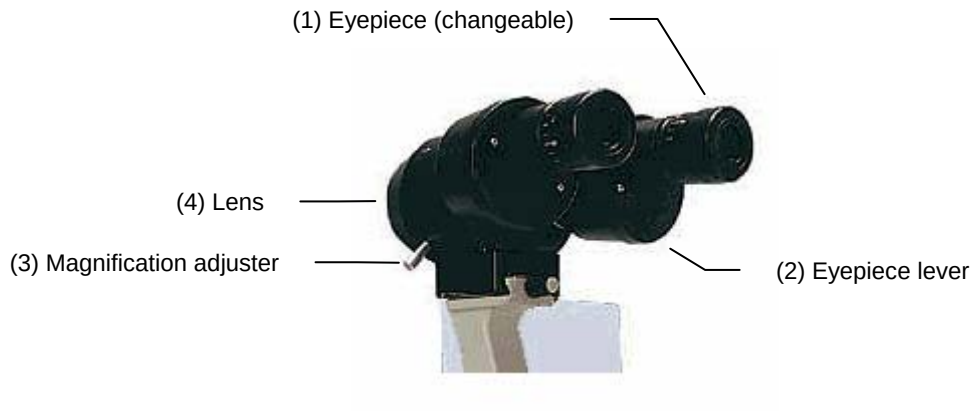


Diagram 4-2: Microscope of the SL-E

The eyepiece (4) with standard 12.5x magnification enables an ametropia equalisation of +/- 5 dpt. By extending or pushing in the eyepiece lever (2), the distance to the pupil can be adjusted.

Magnification adjuster (3): 10 x, 16 x

The slit lamp bon SL-E enables:

- examination of the eye and evaluation of the position of contact lenses with fluorescent light.
- tonometry with a Goldmann tonometer.
- measurement of the cornea and contact lenses with a length measurement eyepiece.

4.3 Slit projector

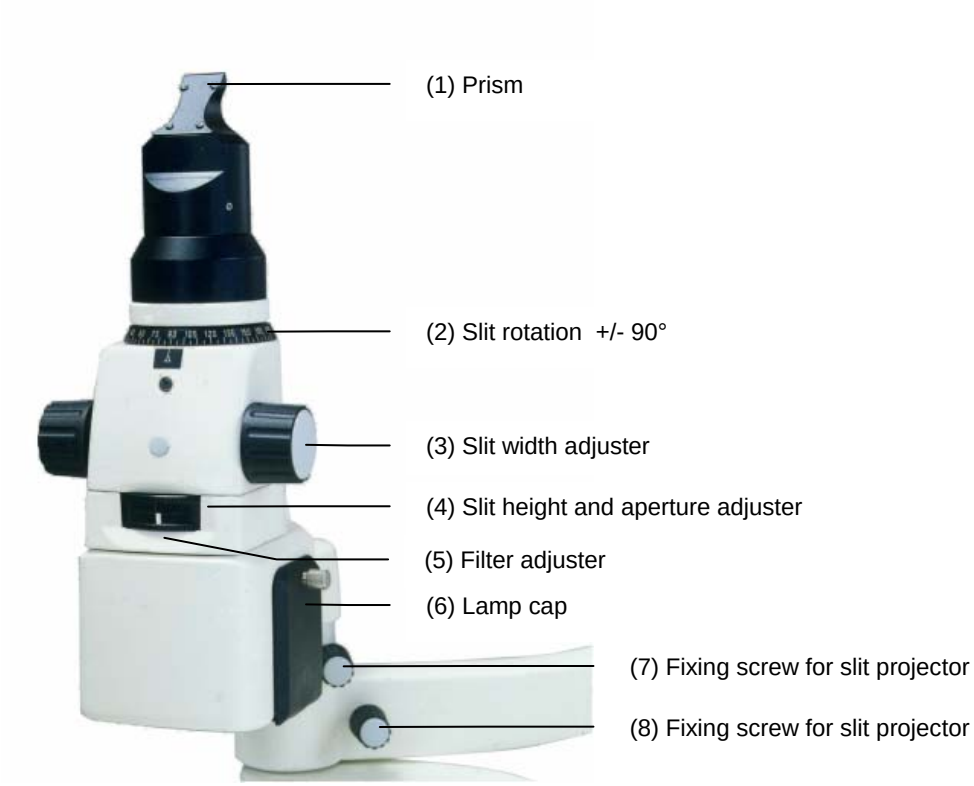

(1) Prism
(2) Slit rotation +/- 90°
(3) Slit width adjuster
(4) Slit height and aperture adjuster
(5) Filter adjuster
(6) Lamp cap
(7) Fixing screw for slit projector
(8) Fixing screw for slit projector

Diagram 4-3: Slit projector

The slit projector offers a wide spectrum of different types of lighting. The slit width (3) can be continuously adjusted from 0 to 14mm. The slit height (4) can be continuously adjusted from 1.8 to 12mm with the optional use of apertures. Green, blue and grey (heat protection) filters can be used as filters (5).

5 Setting-up, assembly and repair

a) Screw the gearwheel plates onto the table base with two recessed-head screws each. Ensure that the sides of the gearwheels face outwards!
b) Screw the Teflon non-slip surface to the table base with four recessed-head screws.
c) Remove a gearwheel from the guiding rod and push it through the base. Then screw the gearwheel back in.
d) Place the base on the table in such a way so that the joystick is situated over the non-stick surface and the gearwheels sit on the gearwheel plate.
e) Place one protective cover to the side of the assembled gear wheel plate and then push the base forward as far as it will go.
f) Check that the top gearwheel is on the last pinion. This is the only way of ensuring that the two gearwheels run parallel.
g) Place the second protective cover on the gearwheel plate.

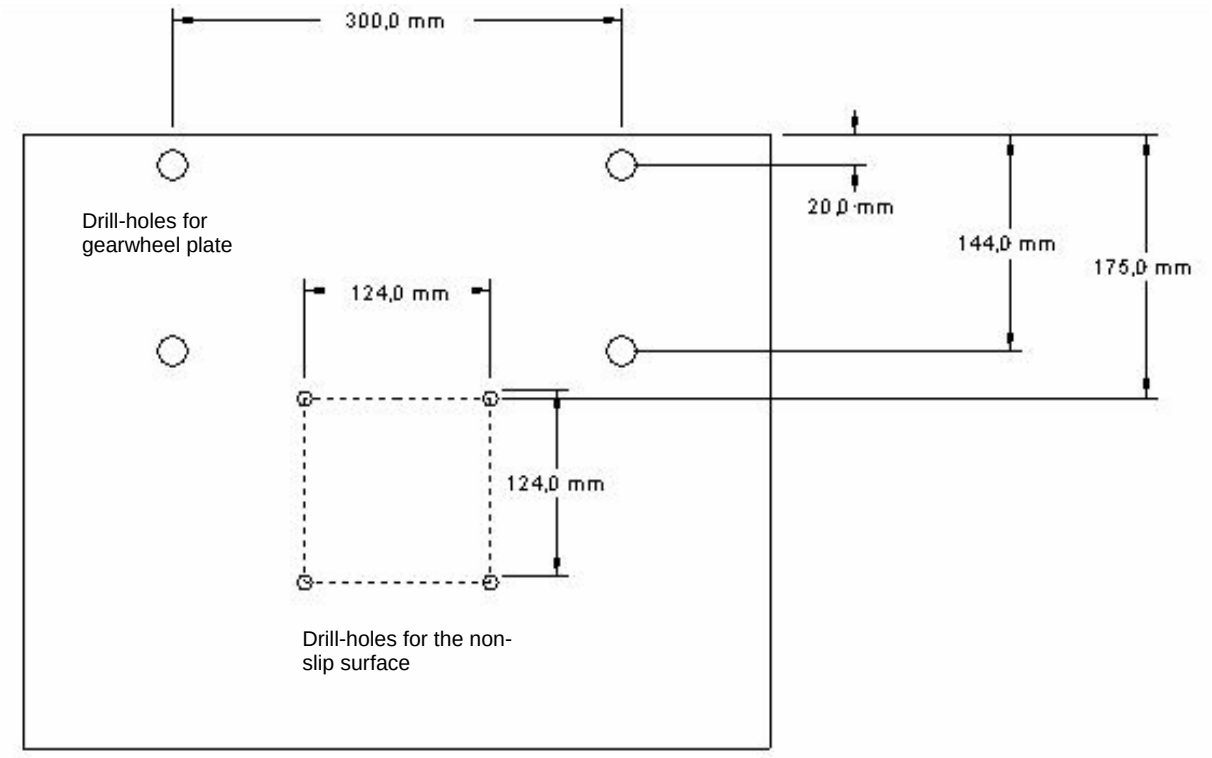


Diagram 5-1: Measurements for drill-holes

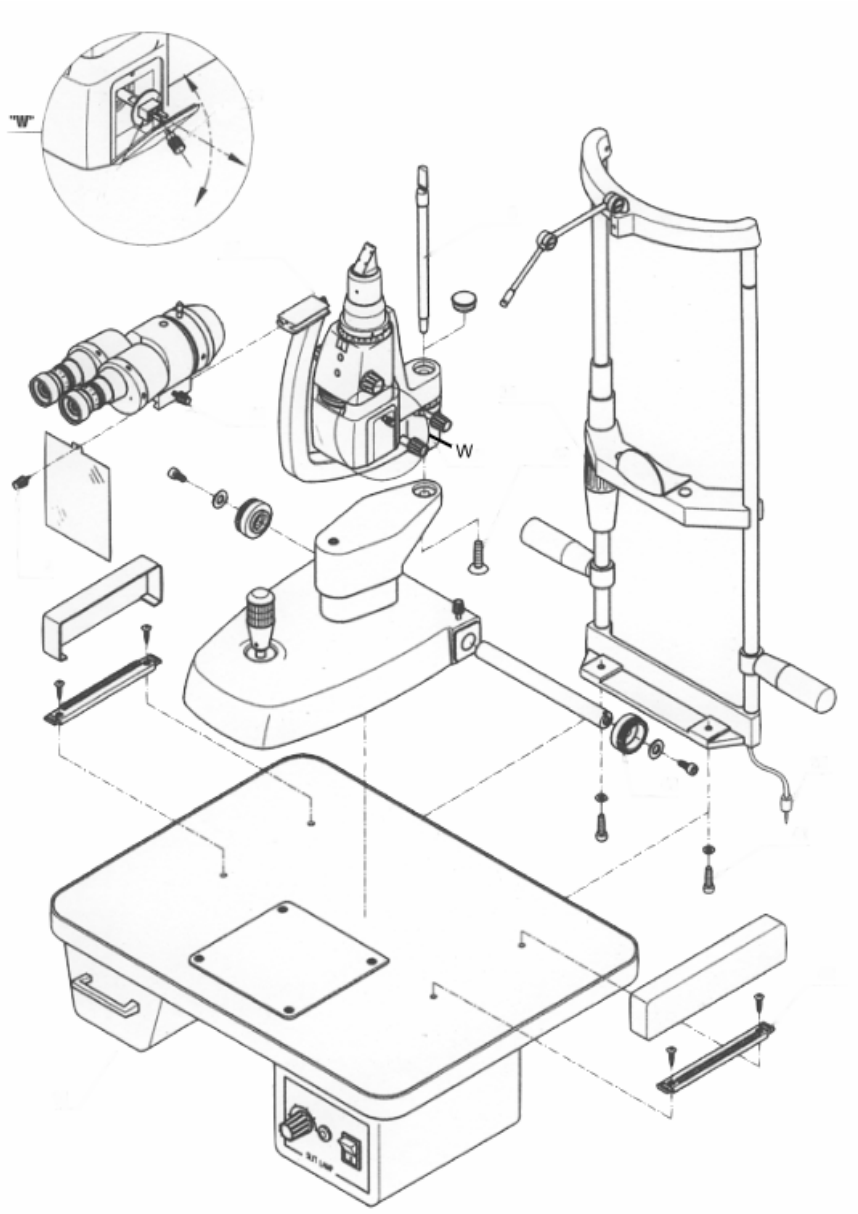
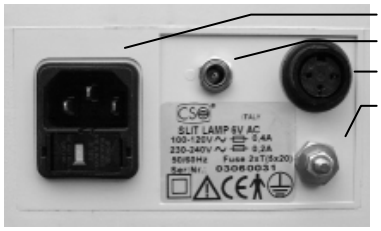


Diagram 5-2: Assembly sketch SL-E

6 Powering-up

The slit lamp can be supplied with electricity by the mains connection or via an examination unit.

a) Mains adaptor:



(1) Mains connection and fuses
(2) Focussing light connection
(3) Slit lamp connection
(4) Protective earth connection

Diagram 6-1: Mains connection- back

Diagram 6-2: Mains connection front

1. Plug the slit lamp into connection (3).
2. Plug the focussing light into connection (2) (optional).
3. Earth the slit limp to connection (4).
4. Plug the mains adaptor (1) into the mains socket using the power cable.
5. Press the on/off switch.

The slit lamp is now ready for use. You can change the brightness of the lamp using the dimmer switch (5).

b) Electricity via an examination unit

Only an expert must install the slit lamp to an examination unit. In particular, please ensure that the supply voltage and power meets the requirements (see chapter on Technical data). Use the appropriate operating controls on your examination unit to power the slit lamp.

7 Operation of the apparatus

7.1 Focussing the microscope

Remove the cap and place the test rod in the holder as shown. Turn the slit lamp on.
Focus the eyepiece so that the grainy surface of the test rod can be seen in focus at medium magnification.

Diagram 7-1:Slit projector

7.2 Examination

- Allow the patient to rest his/her chin comfortably on the chin rest and ensure that his/her forehead is on the forehead rest.
- Use the height adjuster to bring the eyes of the patient up to the level of the marking on the head rest (line of vision height).
- Turn the slit lamp on.
- Look through the microscope and set the desired magnification.
- Centre and focus the eye to be examined with the control lever on the base.
- In order to reduce patients‘ discomfort, the brightness can be adjusted using the mains adaptor.

When directly lighting the eye, the slit of the slit projectors is to be projected in line with the viewing level of the microscope. The height and width of the slit can be adjusted on the slit projector (see diag. 4.3, page 9). With the slit made smaller, the ray of light from the slit lights a small section of the eye, placing it into high contrast. When widened, the section of the eye that can be examined is larger, but the contrast is not so high.

For examination in a red-free image, a green filter is available. Turn the filter dial to the position with the green markings. The blue filter aids observation of intraocular pressure measurements, e.g. with an Applanation tonometer. The grey filter can be used to protect the patient’s eye from heat. The yellow filter on the microscope (see diag. 4.2, page 8) can be used in conjunction with the blue filter for fluorescence observation, e.g. to view the position of contact lenses.

8 Maintenance and care

8.1 Care

Clean the chin rest and the forehead rest on the head rest with a clean damp cloth. Do not use any abrasive or harsh cleaning products! If the lens or eyepiece becomes dirty, please use a soft brush or a lens cleaning cloth.
Do not use disinfection alcohol!

8.2 Maintenance

When used properly, the slit lamp should not require repeated maintenance. For repairs or technical problems please contact the bon Optic customer services department.

8.3 Safety checks

For this device, no special safety checks are required. In order to meet the requirements of the directive on the operation of medical devices, we recommend regular testing of the electrics in connection with the electricity supply.

8.4 Repairs you can carry out yourself

8.4.1 Changing the slit projector lamps

Important
The type of lamp used can vary depending on the version of the product.
Please check which type of lamp is used in your slit lamp:

a) 6V/20W PG 22 – 6.35 (Standard)
b) 12V/20W PG 22 – 6.35

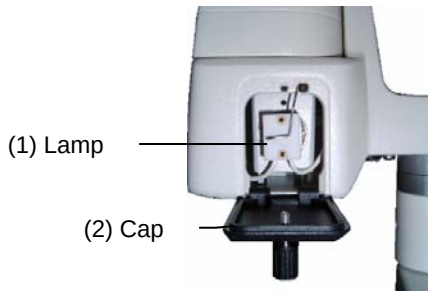


Diagram 8-1: Slit projector lamp

1) Disconnect the slit lamp from the power supply.
2) To avoid burning yourself, leave the lamp to cool for several minutes before changing it.
3) Open the cap (2).
4) Move the clamp to the side and remove the lamp (1) in its holder.
5) Place the new lamp in the holder. Do not touch the glass body of the lamp (to avoid dirtying the lamp!).
6) Place the clamp back in front of the holder and close the cap (2).
7) Check that it works by turning the lamp on.

8.4.2 Changing the focussing light lamp

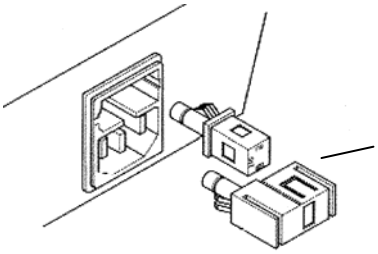
Lamp used: 12 V, 60 mA

1) Disconnect the focussing light from the power supply.
2) Unscrew the red cap from the focussing light and remove the old lamp.
3) Insert the new lamp and screw the red cap back on.

8.4.3 Changing the fuses

Only for original mains adaptor!

Use only fuses with the same fuse values as shown on the mains adaptor.



Diag. 8-2: Mains adaptor (back)

1) Disconnect from the mains before changing the fuse!
2) Open the required fuse element.
3) Remove the old fuse from the holder and replace it with a new fuse of the same type.
4) Place the fuse holder back in the fuse socket.
5) Close the fuse element.

8.5 Power supply disruptions

Should EMC disruptions (**e**lectro-**m**agnetic **c**ompatibility) occur from the mains adaptor, please contact bon Optic customer support.

9 Guarantee and disposal

Should defects as the result of material or production errors occur within 24 months of purchase, we guarantee free-of-charge repair of the ophthalmometer or we will decide whether to offer you a free exchange, provided that:

- A receipt with the date of purchase can be provided.
- The device has been used properly and in accordance with the conditions of use.
- Repairs have not been carried out by anyone other than the bon Optic customer service team or persons authorised by bon Optic.

Guarantee services do not result in extension of the guarantee, nor do they represent the start of a new guarantee. The sales guarantee is not applicable to expendable items.

The terms and conditions of trade of bon Optic also apply.

Disposal

The slit lamp and mains adaptor contain components that should not be disposed of in normal household waste. Please inform the waste disposal company or contact bon Optic.

10 Technical Data

Slit lamp:

Classification (EN 60601-1)	II, Type B
Slit lamp measurements (H/W):	500x380 mm
Weight:	9.5 kg (excl. mains adaptor)
Slit projector halogen lamp:	6V/20W PG 22 (Standard)
Focussing light lamp:	12V/60mA
Slit length (continuous):	1.8 -12 mm
Slit width (continuous):	0-14 mm
Smallest point:	0.3 mm
Maximum slit length:	14 mm
Measurements of the light field:	(0.3/5.5/9/14) mm
Filter:	blue, green,grey
Rotation of the slit:	+/- 90°
Movement of the slit lamp to/from the microscope:	+/- 90°
Magnification:	10x/16x
Ametropia equalisation:	+/- 5 dpt

Base (x,y,z):

Sideways adjustment (left/right):	108 mm (x)
Lengthways adjustment (forwards/backwards):	113 mm (y)
Height adjustment:	approx. 40 mm (z)

Mains adaptor:

Input supply voltage:	100-120V AC / 230-240V AC
Output voltage:	6V AC (slit lamp), 12V AC (focussing light)
Power frequency:	50/60 Hz
Connection power:	40VA
Fuses:	2 x 0.4A T (100-120V) / 2 x 0.2A T (230-240V)
Safety class:	II
Safety type:	IP 21
Device type:	B

Label Symbols	
	Protective earth
	Safety class II (isolated)
	Fuse
	Read instruction manual
	Application part type B

Transport requirements	
	Temperature: -5 °C to +45 °C (+23 °F to +113 °F)
	Air pressure: 650 hPa to 1100 hPa
	Relative humidity: 25% to 80%
Maximum conditions – no longer than 60 days in a row	

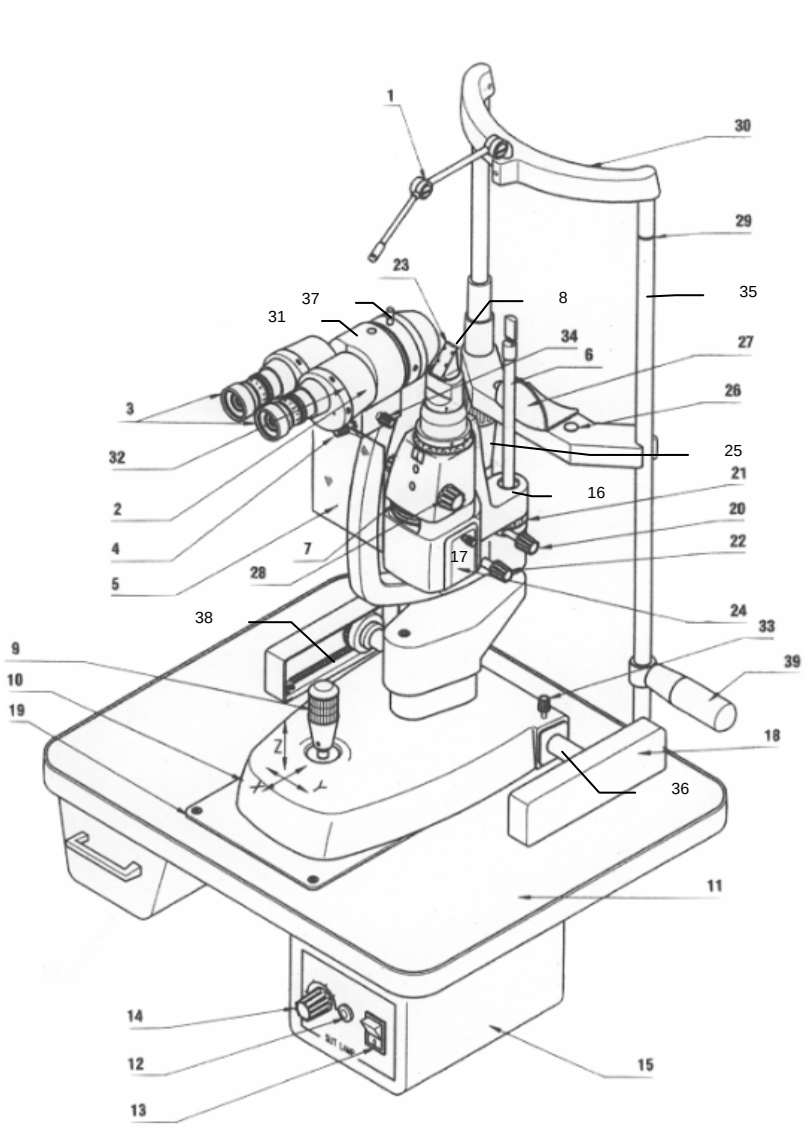


Diagram 10-1: Slit lamp components

1) Focussing light
2) Eyepiece lever
3) Eyepiece (changeable)
4) Screw for mouth cover
5) Mouth cover
6) Test rod
7) Filter and aperture dial
8) Prism
9) Joystick
10) Base with orthogonal movement
11) Table plate
12) Warning light
13) Power switch
14) Dimmer switch
15) Mains adaptor (Transformer)
16) Holder for test rod
17) Lamp (not visible)
18) Running wheel cover
19) Teflon non-slip surface
20) Screw for slit projector
21) Scale for slit projector
22) Screw for moveable arm
23) Prism
24) Lamp cap
25) Head rest height adjuster
26) Chin paper fixing point
27) Chin rest
28) Slit width dial
29) Eye level markings
30) Forehead rest
31) Microscope
32) 2 x extending microscopes
33) Screw for base
34) Screw for microscope
35) Head rest
36) Gear wheel rod
37) Lever for yellow filter (not SL-E)
38) Gear wheel plate
39) Hand rest for head rest

EU – KONFORMITÄTSERKLÄRUNG
EC – DECLARATION OF CONFORMITY

Hersteller-Adresse: (Manufacturer's address)	bon Optic Vertriebsgesellschaft mbH Stellmacherstraße 14 D-23556 Lübeck
Gerätetyp / UMDNS-CODE: (Device type/ UMDNS-CODE)	Spaltlampe (12-281) Slit lamp (12-281)
Gerätebezeichnung: (Device name)	**Spaltlampe SL-72/SL-75/SL-85/SL-E/SL-Zoom** **Slit lamp SL-72/SL-75/SL-85/SL-E/SL-Zoom**
Klassifizierung: (Classification)	**1** (Richtlinie 93/42/EWG, Anhang IX, Regel 1) **1** (MDD 93/42/EEC, appendix IX, rule 1)

Wir erklären hiermit die Übereinstimmung des vorgenannten Produkts mit der EU-Richtlinie 93/42/EWG über Medizinprodukte.

We declare the compliance of the device with the requirements of the Directive 93/42/EEC on medical devices.

Angewandete Normen: (Applicable standards)	DIN EN 60601-1 DIN EN 60601-1-2 EN 1441	(03/96) (09/94) (10/97)
Überwachungsbehörde/ ID-Nr.: (Notified body/ Identification number)	**IMQ / 0051**	

Das Gerät ist gekennzeichnet mit / The device is marked with CE

Lübeck, 01 June 2004

(H. Jochen Kaber, Managing director)